Remarks

Claims 1-18 have been cancelled without prejudice, and Claims 19-33 have been added. The fact that Claims 1-18 have been cancelled without prejudice is not to be construed as an admission by applicants or applicants' attorneys that such claims are not patentable. Applicants reserve the right to prosecute such claims in a continuing application.

Pursuant to 37 C.F.R. §41.50(b), applicants request the reopening of prosecution of the above-identified application in response to the new ground of rejection under 35 U.S.C. §112, first paragraph.

The claims as amended are directed to a method of treating an ongoing auto-immune disease in a human, wherein the disease is selected from the group consisting of psoriasis and diabetes. The method comprises treating the human by administering one or more non-mitogenic anti-CD3 active compounds selected from the group consisting of CD3 antibodies and fragments of CD3 antibodies in an amount effective to treat the disease.

The Board's Decision of January 26, 2005 held that the use of a non-mitogenic anti-CD3 active compound to treat an ongoing autoimmune disease was patentable over the prior art.

The Board, however, found that the claims did not meet the written description requirement of 35 U.S.C. §112, first paragraph, allegedly because applicants did not demonstrate possession of the genus of "anti-CD3 active compounds."

Without agreeing with the Board's Decision, applicants have amended the claims to recite that the non-mitogenic anti-CD3 active compounds are selected from the group consisting of CD3 antibodies and fragments of CD3 antibodies. Applicants believe the amendments obviate the pending rejection.

The Board also rejected claims 1, 2, 4-7, 10-13 and 16-18 for an alleged lack of enablement under 35 U.S.C. §112, first paragraph. Applicants respectfully traverse the rejection.

The pending claims are directed to treating patients with diabetes or psoriasis. The Board held that the specification provides enabling support for treating diabetes. As claims 20, 21 and 25 are limited to such treatments, they are unaffected by the pending rejection. With respect to claims encompassing the treatment of psoriasis, applicants

submit herewith the Declaration of Louis Vaickus, which describes the use of a non-mitogenic anti-CD3 antibody for treating psoriasis.

In his Declaration, Dr. Vaickus describes the treatment of a cohort of four human patients suffering from psoriasis in a clinical trial in which each of the four patients is given 1 mg of TRX4 antibody by intravenous infusion over a period of one hour. TRX4 is a non-mitogenic antibody which recognizes CD3.

Dr. Vaickus states that the patients had Psoriasis Area Sensitivity Index or PASI, scores ranging from 12.2 to 27.0. Within 4 weeks prior to receiving TRX4, none of the patients received any systemic agents for psoriasis treatment nor any immunosuppressive agents. The patients also did not receive any such agents for at least 8 weeks after receiving TRX4.

Immediately after the TRX4 was administered, it was observed that the absolute lymphocyte counts for all patients decreased. The decrease was observed just after completion of the one-hour infusion of TRX4, and was most prominent between days 1 and 2. An increase in the lymphocyte counts began on day 3, and the lymphocyte counts returned to baseline by day 6.

Also, Dr. Vaickus states that modulation of the T-cell receptor was observed most profoundly immediately after the administration of TRX4. There was full recovery of the T-cell receptor complex on the cell surface within 6 days after administration of TRX4.

Dr. Vaickus avers that in patients administered TRX4, serum levels of TRX4 were detected in the blood immediately after completion of the administration of TRX4, and for up to one hour post-administration.

Dr. Vaickus declares that although TRX4 was detected in patient serum for only 1 hour after administration, the patients had reduced lymphocyte counts for only 6 days, and modulation of the T-cell receptor occurred in the patients for only 6 days, all patients showed decreases in their PASI scores from baseline that were durable at least to 8 weeks after administration. At 8 weeks after administration of TRX4, the patients had decreases in their PASI scores of 37.4%, 45.9%, 48.2% and 50.6% from baseline, for an average reduction in PASI score from baseline of 45.5%.

Dr. Vaickus concludes that these results show that a single administration of the TRX4 antibody caused a durable remission of psoriasis for a period of at least 8 weeks, although TRX4 was not detected in patient serum after 4 hours post-administration, and lymphocyte counts had returned to baseline within 6 days of administration.

Thus, applicants have shown, in the specification and in the Declaration of Dr. Vaickus, that, by administering a non-mitogenic anti-CD3 antibody or fragment of a non-mitogenic anti-CD3 antibody, one can effect a durable remission of diabetes or psoriasis. Therefore, applicants have demonstrated that one skilled in the art can practice the claimed invention without undue experimentation. Accordingly, applicants request the rejection be withdrawn.

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In view of the foregoing remarks, a favorable disposition of the application therefore is solicited. The examiner also is invited to contact the undersigned if there are any questions or if the examiner believes that further discussion will advance prosecution.

Respectfully submitted,

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Date

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